UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA, et al. *ex rel.* FOX RX, INC., Plaintiffs, -v- Dr. REDDY'S INC., OMNICARE, INC.; and NEIGHBORCARE, INC., Defendants.	13cv3779 (DLC) OPINION & ORDER

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DENISE COTE, District Judge:

Fox Rx, Inc. ("Fox"), a serial qui tam relator and former Medicare Part D plan sponsor, brings this action under the federal False Claims Act, 31 U.S.C. § 3729 et seq. ("FCA"), and twenty-two states', the District of Columbia's, and two cities' false claims laws against defendants Omnicare, Inc. and its

subsidiary NeighborCare, Inc. (together, "Omnicare"), a long-term care ("LTC") pharmacy, and against drug manufacturer Dr. Reddy's Laboratories, Inc. ("Dr. Reddy's"). After searching through old claim submissions, Fox has filed a number of qui tam actions under the False Claims Act against pharmacies Fox once worked with, among others. This is one such action. Fox filed two others in this district, including one against Omnicare, which were recently dismissed for failure to state a claim. United States ex rel. Fox Rx, Inc. v. Omnicare, Inc., --- F. Supp. 2d ---, 2014 WL 3928780 (S.D.N.Y. Aug. 12, 2014); United States ex rel. Fox Rx, Inc. v. Walgreen Co., 2014 WL 4066223 (S.D.N.Y. Aug. 18, 2014). Omnicare and Dr. Reddy's now move to dismiss the Second Amended Complaint ("SAC") in this action. For the reasons given below, these motions are granted.

BACKGROUND

In broad strokes, the SAC alleges that the defendants have engaged in two illegal practices. Fox asserts that (1) a drug rebate Dr. Reddy's provided to Omnicare was an illegal kickback, and (2) Omnicare improperly billed the federal government ("Government") for dispensing fees in certain circumstances. By engaging in such practices, Fox asserts that the defendants caused false claims to be submitted to the Government and overcharged Medicare. The following allegations are drawn from the SAC and documents integral to it, as well as certain

Government documents concerning Medicare of which the Court takes judicial notice.[1]

I. The Parties

The relator is Fox Rx, Inc., the corporate parent of Fox Insurance, Inc. (together, "Fox"). From 2006 to 2010, Fox sponsored prescription drug plans pursuant to the Government's Part D prescription drug benefit program.[2] Fox asserts that it, along with the Government and the states, was a victim of the defendants' fraudulent practices.

Defendant Omnicare provides pharmacy services to LTC facilities ("LTCFs"). Through contracts with LTCFs, Omnicare serves as a consulting pharmacist and dispenses drugs to approximately 1.4 million LTCF residents in 47 states and the District of Columbia. The SAC alleges that Omnicare operated under a Corporate Integrity Agreement with the Centers for Medicare & Medicaid Services ("CMS") that "specifically covered 'Arrangements' with vendors such as Dr. Reddy's and specifically addressed measures to protect against kickback schemes as alleged in this complaint." No further details concerning this

[1] Judicial notice may be taken of a public record pursuant to Rule 201(b), Fed. R. Evid. See Bryant v. New York State Educ. Dep't, 692 F.3d 202, 208 (2d Cir. 2012) ("[A] reviewing court can consider . . . public records when considering a motion to dismiss.") (citation omitted).

[2] In 2010, the Government terminated Fox's contract.

Agreement are alleged, and the Agreement is not attached to the SAC.

Defendant Dr. Reddy's is an India-based pharmaceutical company that manufactures generic drugs including simvastatin. Simvastatin is used for the treatment of high cholesterol and the prevention of cardiovascular disease.

Before describing the allegations regarding the defendants' purportedly illegal practices, the Government programs at issue and other information critical to understanding those allegations will be described. The Government programs are Medicare Part D and Part A and Medicaid.

II. Federal Programs At Issue

A. Medicare Part D

The SAC asserts that the defendants defrauded the Government's Medicare Part D program. Medicare is a federally funded health insurance program for the elderly and disabled. CMS, a component of the United States Department of Health and Human Services ("HHS"), administers the Government's Medicare and Medicaid programs. 42 U.S.C. §§ 1395, 1396. In December 2003, Congress passed the Medicare Prescription Drug, Improvement, and Modernization Act ("MMA"), which established a voluntary prescription drug benefit program for Medicare enrollees known as Medicare Part D. Pub. L. No. 108-173, 117 Stat. 2066, codified at 42 U.S.C. § 1395w-101 et seq.

To provide Part D benefits to enrollees, Medicare enters into contracts with private companies known as Part D sponsors. The sponsors administer prescription drug plans. Fox was one such sponsor.

The sponsors may contract with pharmacies and pharmacy networks to provide the prescription drugs to Part D beneficiaries who have enrolled in their plans. When a Medicare Part D beneficiary has a prescription filled, the pharmacy presents a claim to the sponsor. The sponsor then notifies CMS of the transaction, including the cost the sponsor incurred in making a payment to the pharmacy.

CMS provides advance monthly payments to sponsors based on a subsidy per enrollee in the sponsor's program and on estimates of the subsidies CMS will be required to pay to the sponsors. At the end of a payment year, CMS reconciles the advance payments it made to the sponsor and the actual costs the sponsor has incurred. To the extent that the sponsor paid out more than it received in advance payments from CMS, CMS may provide the sponsor with additional payments, which are calculated according to a complex regulatory formula. See 42 C.F.R. § 423.336 (a)-(b).

Part D sponsors may also enter into contracts with pharmacy benefit managers ("PBMs") to create a pharmacy network and to administer the sponsors' prescription drug programs. CMS

regulations require that the contracts between sponsors and either PBMs or pharmacies contain language obligating the pharmacy to comply with federal law and CMS instructions.

When pharmacies dispense drugs to a Medicare Part D enrollee, they submit a claim electronically to the enrollee's sponsor, often through a PBM. The claim contains information about the cost of the drug, the dispensing fee, any taxes paid, any payments made by the enrollee, and any rebates received from the drug's manufacturer or distributor. It is the plan sponsor that is responsible for submission of data to CMS.

B. Medicare Part A

According to the SAC, Medicare Part A is a program that covers, among other things, the cost of prescription drugs for residents of LTCFs for the first 100 days of a resident's stay. During those 100 days, LTCFs receive per diem payments for that resident from the Part A program, which are used to reimburse pharmacies like Omnicare for drugs prescribed to the resident. Pharmacies bill the LTCF for these prescriptions, not the Government. The Part A per diem payments from the Government for a given resident do not change as a result of the drugs prescribed the resident. Following those 100 days, prescription drug benefits under other Medicare Programs, including Part D, may be provided.

The cost of a given prescription may be split among an LTCF (covered by Part A) and Medicare Part D where a resident's Part A coverage ends in the middle of a prescription supply period and the resident is then eligible for Part D benefits (a "Part A-Part D Transition"). In the case of a Part A-Part D Transition, the pharmacy may request reimbursement from both the LTCF, for the drugs to be consumed during the remainder of the resident's Part A coverage period, as well as from a Part D plan sponsor, for the remainder of the drugs.

C. Medicaid

The SAC also claims that the defendants defrauded the Government's Medicaid program. Medicaid is a cooperative program between the Government and the states that provides health care benefits principally to the indigent and to disabled individuals. To qualify for federal Medicaid funds, a state must comply with minimum federal standards.

The Medicaid statute requires participating states to pay for prescription drugs. Pharmaceutical manufacturers that want their drugs to be eligible for payment by Medicaid are required to enter into a Rebate Agreement with CMS under which they agree to give state Medicaid programs discounts through a quarterly rebate payment that is calculated based on the utilization of the drug by the state's Medicaid program beneficiaries.

III. Reimbursement to Pharmacies Under Plan D

Under Plan D, pharmacies like Omnicare are generally reimbursed for dispensing drugs based on the average wholesale price ("AWP") or maximum allowable cost ("MAC") for a given drug. See Office of Inspector General, Department of Health and Human Services, Comparing Pharmacy Reimbursement: Medicare Part D to Medicaid at 2-3 (2009). For example, under a contract quoted in the SAC, a PBM would pay Omnicare a percentage of AWP plus a dispensing fee for brand-name drugs and a percentage of MAC plus a dispensing fee for generic drugs. These amounts paid did not depend upon the actual price a pharmacy paid for a given drug. Both PBMs and pharmacies negotiate prices, including rebates, with drug manufacturers. See In re Pharm. Indus. Average Wholesale Price Litig., 230 F.R.D. 61, 72 (PBMs), 74 (pharmacies) (D. Mass. 2005); see also Astrazeneca AB v. Apotex Corp., 985 F. Supp. 2d 452, 468-69 (S.D.N.Y. 2013) (discussing health plan, PBM, and pharmacy negotiations of prices with drug manufacturers and noting "[p]harmacists customarily stock a single generic product").

A "dispensing fee" is defined, for purposes of Part D reimbursement, as "costs that [a]re incurred at the point of sale and pay for costs in excess of the ingredient cost of a covered Part D drug each time a covered Part D drug is dispensed" and "[i]nclude only pharmacy costs associated with

ensuring that possession of the appropriate covered Part D drug is transferred to a Part D enrollee." 42 C.F.R. § 432.100. These costs include "any reasonable costs associated with" activities ranging from "measurement or mixing of the covered Part D drug [and] filling the container" to "a pharmacist's time in checking the computer for information about an individual's coverage" and "performing [certain] quality assurance activities" to "salaries of pharmacists and other pharmacy workers as well as the costs associated with maintaining the pharmacy facility and acquiring and maintaining technology and equipment necessary to operate the pharmacy." Id. A dispensing fee should "not include administrative costs incurred by the Part D plan in the operation of the Part D benefit, including system costs for interfacing with pharmacies." Id.

IV. Omnicare's Contract with ProCare

ProCare was a PBM that worked both with Fox, as sponsor, and with Omnicare. ProCare entered into a contract with Omnicare that addressed Omnicare's claims for drugs prescribed over a Part A-Part D Transition, providing that Omnicare could file a Part D claim with ProCare for a fraction of the "Ingredient Charge" equal to the fraction of days in the prescription supply period that would fall under Part D coverage, and that "any such Claim shall not include a

Dispensing Fee." That contract is not further described in, or attached to, the SAC.

V. Rebate Disclosures

Beginning in January 2007, CMS collected LTC pharmacy rebate data from Part D sponsors, based on concerns that "LTC network pharmacies receive access/performance rebates that may create financial incentives that conflict with Part D sponsors' formularies or drug utilization management (DUM) programs" ("CMS Rebate Data"). Omnicare reported, in connection with the collection of CMS Rebate Data, that in 2007 it received a rebate from Dr. Reddy's on simvastatin of between 2 and 4 cents per tablet. Three other pharmacies that filed claims under Fox's Part D plan -- AccessHealth, MHA Long Term Care Network ("MHA"), and American Pharmacy Network Solutions ("APNS") -- also reported receiving rebates from Dr. Reddy's on simvastatin in 2007. AccessHealth received rebates ranging from 43 cents to $37.16 per unit; MHA's rebates ranged from 5 cents per tablet, or $19.68 per unit, to $59.03 per unit; APNS's rebate was 58 cents per unit. The SAC alleges that Omnicare was "by far the largest recipient of Dr. Reddy's simvastatin rebates" in 2007.

On November 24, 2008, CMS suspended the collection of that data for the years 2008 and 2009, noting concerns about the efficacy of such data. The SAC alleges that Omnicare has not

reported receiving rebates from Dr. Reddy's for simvastatin for the years 2008, 2009, and 2010.

VI. Allegations

On June 3, 2013, Fox brought this action against Omnicare and Dr. Reddy's, alleging two different sorts of misconduct. Of the Government, the twenty-two states, the District of Columbia, and the two cities on whose behalf Fox brought suit, none has elected to intervene.

First, Fox alleges that, between 2007 and 2010, Dr. Reddy's provided a per-unit rebate to Omnicare on the drug simvastatin in violation of the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b ("Rebates Claim"). Fox alleges that, according to its own records, between 2007 and 2010 more than 90% (and in some years, nearly 100%) of the simvastatin dispensed by Omnicare to Fox's plan members was manufactured and sold by Dr. Reddy's. Fox cites no further evidence of rebates paid by Dr. Reddy's to Omnicare for the years 2008, 2009, and 2010. Fox alleges "the existence of multiple manufacturers who sold the same generic equivalent at lower prices during the relevant period."

Fox further alleges, in support of its Rebates Claim, that other pharmacies purchased a lower percentage of their simvastatin from Dr. Reddy's than Omnicare did between 2007 and 2010. For example, Good Neighbor Pharmacy Provider Network purchased 37% of its simvastatin from Dr. Reddy's in 2009;

AccessHealth purchased 6% between 2007 and 2010; and MHA purchased 18% during the same period. Fox also alleges that Omnicare "charged more" for Dr. Reddy's simvastatin in the same dosages than other pharmacies did. In support, Fox attaches charts indicating that the "ingredient cost" reported by pharmacies for Dr. Reddy's simvastatin varied, and that in some instances Omnicare's reported ingredient cost was higher for a given dosage than one or more other pharmacies'. Fox has conceded, in its opposition papers, that Omnicare was reimbursed for dispensing simvastatin to Plan D beneficiaries according to the relevant AWP or MAC, not the ingredient cost.

Second, Fox alleges that from 2007 to 2010, Omnicare has improperly billed dispensing fees to Medicare Part D where a prescription straddled a Part A-Part D Transition (the "Dispensing Fees Claim"). Fox alleges that either Omnicare double-billed, because it also billed the LTCF for a dispensing fee, or that it must have engaged in an illegal "swapping" kickback scheme by agreeing not to charge the fee "in exchange for those facilities providing Omnicare access to the facilities' patients and the opportunity to submit Part D claims." No other facts evidencing such a scheme are alleged.

VII. Defendants' Motions to Dismiss

On August 8, 2014, Omnicare and Dr. Reddy's each moved to dismiss Fox's Second Amended Complaint. In its opposition

papers of September 9, Fox consented to the dismissal of all but its federal claims. The motions were fully submitted on September 23.

DISCUSSION

I. Legal Standards

A. Motion to Dismiss

When considering a motion to dismiss under Rule 12(b)(6), a court must accept as true all allegations in the complaint and draw all reasonable inferences in the plaintiffs' favor. Keiler v. Harlequin Enters. Ltd., 751 F.3d 64, 68 (2d Cir. 2014). The claims raised in the SAC require application of both the ordinary and heightened pleading standards in the Federal Rules of Civil Procedure. The ordinary pleading standard is set forth in Rule 8(a), Fed. R. Civ. P., which requires "a short and plain statement of the claim showing that the pleader is entitled to relief." Under Rule 8(a), to survive a motion to dismiss, "a complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face." Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) (citation omitted). A complaint must do more, however, than offer "naked assertions devoid of further factual enhancement." Id. (citation omitted). The court is "not bound to accept as true a legal conclusion couched as a factual allegation." Id. (citation omitted). Accordingly, a court may disregard "[t]hreadbare recitals of the

elements of a cause of action, supported by mere conclusory statements." Id.

Applying the plausibility standard is "a context-specific task that requires the reviewing court to draw on its judicial experience and common sense." Id. at 679. "Plausibility depends on a host of considerations: the full factual picture presented by the complaint, the particular cause of action and its elements, and the existence of alternative explanations so obvious that they render plaintiff's inferences unreasonable." Fink v. Time Warner Cable, 714 F.3d 739, 741 (2d Cir. 2013) (citation omitted). Although the focus should be on the pleadings in considering a motion to dismiss, the court will deem the complaint to include "any written instrument attached to it as an exhibit, materials incorporated in it by reference, and documents that, although not incorporated by reference, are 'integral' to the complaint." L-7 Designs, 647 F.3d at 422 (citation omitted).

In addition, because Fox's claims allege fraud, they must also meet the heightened pleading standard set out in Rule 9(b). See Gold v. Morrison-Knudsen Co., 68 F.3d 1475, 1477 (2d Cir. 1995) (per curiam). Rule 9(b) requires plaintiffs to "state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b). In order to comply with Rule 9(b), a complaint must "(1) specify the statements that the

plaintiff contends were fraudulent, (2) identify the speaker, (3) state where and when the statements were made, and (4) explain why the statements were fraudulent." Nakahata v. New York-Presbyterian Healthcare System, Inc., 723 F.3d 192, 197-98 (2d Cir. 2013) (citation omitted). Under Rule 9(b) "[m]alice, intent, knowledge, and other conditions of a person's mind may be alleged generally." Fed. R. Civ. P. 9(b). Nonetheless, "plaintiff[s] must allege facts that give rise to a strong inference of fraudulent intent." Nakahata, 723 F.3d at 198 (citation omitted); see also Acito v. IMCERA Group, Inc., 47 F.3d 47, 52 (2d Cir. 1995). The inference "may be established either (a) by alleging facts to show that defendants had both motive and opportunity to commit fraud, or (b) by alleging facts that constitute strong circumstantial evidence of conscious misbehavior or recklessness." Lerner v. Fleet Bank, N.A., 459 F.3d 273, 290-91 (2d Cir. 2006) (citation omitted).

B. False Claims Act

The FCA creates liability when a person

> (A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
>
> (B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim; [or]
>
> [. . .]
>
> (G) knowingly makes, uses, or causes to be made or used, a false record or statement material to an

> obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government.

31 U.S.C. § 3729(a)(1).[3] The FCA defines "claim" to include any request for money directed to (i) the United States or (ii) a "contractor, grantee, or other recipient," where the money "is to be spent or used on the Government's behalf or to advance a Government program or interest" and the Government either provides some portion of the money requested or "will reimburse such contractor, grantee, or other recipient for any portion of the money." Id. at § 3729(b)(2)(A). The FCA defines "knowingly" as either possessing actual knowledge or as acting in deliberate ignorance of falsity or action in reckless disregard of falsity, and not to require "proof of specific intent to defraud." Id. at § 3729(b)(1). A false record or statement is "material" to a false or fraudulent claim if it has "a natural tendency to influence, or [is] capable of

[3] The False Claims Act was amended by the Fraud Enforcement and Recovery Act of 2009 ("FERA") to broaden liability by eliminating certain limitations on FCA claims. See Pub. L. 111-21 § 4(a), 123 Stat. 1617, 1621-23. FERA became effective on May 20, 2009, except for the amended subsection (a)(1)(B), which applied "to all claims under the [FCA] that [we]re pending on or after" June 7, 2008. FERA § 4(f), 123 Stat. at 1625. Fox alleges false claims from 2007 through 2010. Because the Court holds that Fox has failed to state a claim under the broader, post-FERA statute, Fox's claims would fare no better under the pre-FERA provisions.

influencing, the payment or receipt of money or property." Id. at § 3729(b)(4).

A certification may be either factually or legally false. A factually false certification is one that involves "an incorrect description of goods or services provided or a request for reimbursement for goods or services never provided." Mikes v. Straus, 274 F.3d 687, 697 (2d Cir. 2001). A legally false certification is one that relies "upon a false representation of compliance with a federal statute or regulation or a prescribed contractual term." Id. at 696. Noncompliance with regulations that are "irrelevant" to the Government's disbursement decisions, however, do not constitute legally false certifications since the FCA is "aimed at retrieving ill-begotten funds." Id. at 697. "[O]nly where a party certifies compliance with a statute or regulation as a condition to governmental payment" is there a violation of the FCA based on a legally false certification. Id.

Because state and local agencies are best suited to monitor quality of care issues in the health care industry, an impliedly false certification theory of liability is only available "in limited circumstances" in connection with Government health care reimbursement claims. Id. at 700. Thus, a claim of liability based on an implied false certification is viable "only when the underlying statute or regulation upon which the plaintiff relies

expressly states the provider must comply in order to be paid." Id. Statutory or regulatory provisions "establish[ing] conditions of participation" in a federal health care program are to be distinguished from those setting forth "prerequisites to receiving reimbursement." Id. at 701-02.

C. Anti-Kickback Statute

The Anti-Kickback Statute provides, in relevant part, that

> (1) whoever knowingly and willfully solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind . . . in return for purchasing . . . or recommending purchasing . . . any good . . . for which payment may be made in whole or in part under a Federal health care program, shall be guilty of a felony . . . .
>
> (2) whoever knowingly and willfully offers or pays any [such] remuneration . . . shall be guilty of a felony . . . .
>
> (3) Paragraphs (1) and (2) shall not apply to --
>
> > (A) a discount or other reduction in price obtained by a provider of services or other entity under a Federal health care program if the reduction in price is properly disclosed and appropriately reflected in the costs claimed or charges made by the provider or entity under a Federal health care program; [and]
> >
> > [. . .]
> >
> > (E) any payment practice specified by the Secretary in [certain] regulations . . . .

42 U.S.C. § 1320a-7b(b).

Those regulations provide that the Anti-Kickback Statute does not reach discounts provided to the buyer "in whose name a

claim or request for payment is submitted for the discounted item or service and payment may be made, in whole or in part, under Medicare, Medicaid or other Federal health care programs" provided that the following two conditions are met:

> (A) The discount must be made at the time of the sale of the good or service or the terms of the rebate must be fixed and disclosed in writing to the buyer at the time of the initial sale of the good or service; and
>
> (B) the buyer (if submitting the claim) must provide, upon request by the Secretary or a State agency, information provided by the seller as specified in . . . this section, or information provided by the offeror as specified in . . . this section.

42 C.F.R. § 1001.952(h)(1)(iii).

Similarly, these regulations offer a safe harbor to those who sell to such buyers where the following two conditions are met:

> (A) Where the seller submits a claim or request for payment on behalf of the buyer and the item or service is separately claimed, the seller must provide, upon request by the Secretary or a State agency, information provided by the offeror as specified in . . . this section; or
>
> (B) Where the buyer submits a claim, the seller must fully and accurately report such discount on the invoice, coupon or statement submitted to the buyer; inform the buyer in a manner reasonably calculated to give notice to the buyer of its obligations to report such discount and to provide information upon request under paragraph (h)(1) of this section; and refrain from doing anything that would impede the buyer from meeting its obligations under this paragraph.

42 C.F.R. § 1001.952(h)(2)(iii).

II. Rebates Claim

Fox's Rebates Claim fails because the rebates allegedly accepted by Omnicare fall within the regulatory safe harbors for discounts, and therefore do not constitute a violation of the Anti-Kickback Statute. See 42 C.F.R. § 1001.952(h)(1)-(2). As reflected above, the receipt of rebates is an integral feature of the negotiations between pharmacies and drug manufacturers. And, CMS had collected data from pharmacies about their receipt of such rebates. It is not surprising, therefore, that Government regulations address rebate practices and describe the conditions under which a rebate program is exempt from the Anti-Kickback Statute.

As described above, pursuant to federal regulations, the buyer of a pharmaceutical drug is exempt from the Anti-Kickback Statute if it is an entity "in whose name a claim or request for payment is submitted for the discounted item or service and payment may be made, in whole or in part, under Medicare," provided (1) the per-unit rebates were "fixed" at the time of the sale to the buyer, and (2) the rebates were disclosed to the buyer in writing at the time of sale. Id. at § 1001.952(h)(1)(iii)(A). Fox has not alleged that any of these conditions did not apply to Omnicare as the buyer of drugs. Nor does Fox allege that

Omnicare has failed to respond to a request for rebate information by the Secretary of the Department of Health and Human Services ("Secretary") or a state agency. Id. at § 1001.952(h)(1)(iii)(B). Indeed, Fox alleges that it learned of Omnicare's 2007 rebate agreement from Omnicare's own reporting of that rebate. Accordingly, Fox has failed to plead that Omnicare's acceptance of the rebate ran afoul of the Anti-Kickback Statute.

Dr. Reddy's provision of the rebate is protected by the parallel safe harbor for sellers. Id. at § 1001.952(h)(2)(iii). Fox does not allege that Dr. Reddy's failed to "fully and accurately report such discount on the invoice, coupon or statement submitted to" Omnicare, that Dr. Reddy's failed to "inform [Omnicare] in a manner reasonably calculated to give notice to [Omnicare] of its obligations to report such discount and to provide information upon request," or that Dr. Reddy's did "anything that would impede [Omnicare] from meeting its obligations" under that provision. Id. at § 1001.952(h)(2)(iii)(B). Nor does Fox allege that Dr. Reddy's failed to respond to a request by the Secretary or a state agency. Id. at § 1001.952(h)(2)(iii)(A).

Fox's only argument to the contrary is based on a misreading of this regulation. Fox argues that

subparagraph (ii), not subparagraph (iii), applies to Omnicare. Yet, subparagraph (ii) applies where "the buyer is an entity which reports its costs on a cost report required by the Department or a State health care program." Fox has not alleged that Omnicare "reports its costs on a cost report," nor could it, since cost reports are required of "Medicare-certified institutional providers" like hospitals, health clinics, home health agencies, and hospices -- not pharmacies. See CMS, Cost Reports, available at http://www.cms.gov/Research-Statistics-Data-and-Systems/Files-for-Order/CostReports/index.html (last visited December 1, 2014). Accordingly, Fox's Rebates Claim is dismissed as to both Omnicare and Dr. Reddy's.[4] Since Fox does not plausibly allege an unlawful kickback, the Court need not decide whether a violation of the Anti-Kickback Statute can form the basis of an FCA claim under the two regulatory provisions cited by Fox. See 42 C.F.R. § 423.505(i)(3)(iii), (4)(iv).

[4] Fox also alleges "reverse" false claims for Omnicare's failure "to remit rebates to the Government to which it is entitled" as a result of supposed overcharging due to Omnicare's failure to report rebates. As explained above, Fox has failed to allege these rebates were illegal. Nor has Fox plausibly alleged that the Government was overcharged as a result of these rebates. Accordingly, Fox's "reverse" false claims related to the rebates fail to state a claim.

III. Dispensing Fees Claim

Fox's Dispensing Fees Claim fails because the conduct Fox actually alleges -- Omnicare charged a dispensing fee to Medicare Part D for prescriptions that bridged a Part A-Part D Transition -- did not render any Part D claims factually or legally false.[5] Fox claims that this charge is in violation of 42 U.S.C. § 1395w-102(e)(2)(B), which provides that a drug is not covered by Medicare Part D "if payment for such drug as so prescribed and dispensed or administered . . . is available (or would be available but for the application of a deductible) under part A or B . . . ." Yet, as Fox admits, the LTCF (under Part A) covers only a portion of a prescription across a Part A-Part D Transition; Fox concedes in the SAC that in such a case, "the LTC pharmacy may be entitled to submit a claim to a Part D plan for payment for the remaining supply of dispensed drugs."

Nor does the definition of "dispensing fee" suggest that it would be improper to split this fee between the LTCF (under Part A) and the Part D sponsor. As noted above, a "dispensing fee"

[5] Because Fox has failed to state a valid claim, the Court need not reach defendants' alternative argument that Fox's claims are barred by the doctrine of res judicata following the dismissal of another FCA suit by Fox, as relator, against Omnicare that alleged, among other things, that Omnicare unlawfully split prescriptions, filling prescriptions for a longer period several times across smaller periods, in order to enhance its dispensing fees. See August 29, 2012 Opinion, United States ex rel. Fox Rx, Inc. v. Omnicare, Inc., 11cv962 (N.D. Ga.), Dkt. No. 96.

may include "pharmacy costs associated with ensuring that possession of the appropriate covered Part D drug is transferred to a Part D enrollee," defined to encompass not just the "measurement or mixing of the covered Part D drug [and] filling the container," but also "any reasonable costs associated with," for example, "maintaining the pharmacy facility and acquiring and maintaining technology and equipment necessary to operate the pharmacy." 42 C.F.R. § 432.100. Fox points to no statutory or regulatory provision that would prohibit such a split.

Fox's only rejoinder is that it believes Omnicare did not split the dispensing fee, but charged a full dispensing fee to Medicare Part D, because the fee charged for the Part A-Part D Transition prescriptions appears to be Omnicare's standard Part D dispensing fee. Yet, Fox points to no statute or regulation that prohibits the full allocation of dispensing fees to Medicare Part D. For any amount of drugs dispensed, the price claimed is to "include any dispensing fees for such drugs." 42 U.S.C. § 1395w-102(d)(1)(B). Indeed, Fox concedes that Omnicare accurately reported the amount of drugs covered by Part D. That this amount corresponded to some, rather than all, of a particular prescription does not change the costs of responsibly dispensing those drugs. Fox has not plausibly alleged that Omnicare caused the submission of a claim with "an incorrect description of goods or services provided or a request for

reimbursement for goods or services never provided," or with "a false representation of compliance with a federal statute or regulation or a prescribed contractual term [with the Government]." Mikes, 274 F.3d at 696-97.

Finally, Fox argues that Omnicare may have double-billed its dispensing fee in these circumstances, charging its standard dispensing fee to both the LTCF (under Part A) and to Part D. But, Fox does not allege Omnicare actually did so. Fox alleges that Omnicare either double-billed or "waived its Part A dispensing fees to the [LTCFs] in exchange for access to the facility's patients and the opportunity to bill the United States under Medicare Part D." Fox alleges no facts to support its suggestion that Omnicare did something "in exchange for access to [LTCFs'] patients." Without any other allegations concerning this "exchange," this bare allegation is implausible speculation. Accordingly, Omnicare may have double-billed, or it may not have. Fox's allegation of the "sheer possibility" of double-billing does not state a claim under the FCA. Iqbal, 556 U.S. at 678.

CONCLUSION

Omnicare's and Dr. Reddy's August 8, 2014 motions to dismiss Fox's Second Amended Complaint are granted. The Clerk

of Court is directed to close this case.

SO ORDERED:

Dated: New York, New York
December 1, 2014

DENISE COTE
United States District Judge